**Draft Guidance for Plant Biostimulant Products**
**Plant Biostimulants and Label Claims Excluded or Regulated under FIFRA as Plant Regulators**

**Executive Summary:** This guidance is intended to establish which biological substances and mixtures, and associated product label claims are or are not considered to be plant regulators by the Agency and, therefore, subject to regulation under FIFRA as pesticides. This guidance does not address or attempt to provide a regulatory definition for "plant biostimulant" or for "nutritional chemical." As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice.

**Background:** Plant biostimulants (PBS) are a relatively new, but growing category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth, enhance resistance to plant pests, and reduce abiotic and biotic stress. The increasing popularity of PBS arises from their ability to enhance agricultural productivity by stimulating natural processes in the plant and in soil using substances and microbes already present in the environment. PBS can promote greater water and nutrient use efficiency but do not provide any nutritionally-relevant fertilizer benefit to the plant. PBS products are becoming increasingly attractive for use in sustainable agriculture production systems and integrated pest management (IPM) programs, which in turn can reduce the use of conventional chemical pesticides. The known capacity of many PBS products to physiologically influence the growth and development of plants results in these products being considered plant regulators by the Agency. FIFRA Section 2(u) defines plant regulators as pesticides, so they are subject to federal licensing as pesticides under FIFRA.

The presence in PBS products of naturally-occurring plant growth substances (plant regulators), as well as claims for plant regulator activity on the product labels, may trigger regulation of a PBS product under FIFRA as a pesticide. Alternatively, many of these same substances and products may be excluded or exempt from regulation under FIFRA depending upon their intended uses as plant nutrients (*e.g.* fertilizers), plant inoculants, soil amendments, and vitamin-hormone products. These exclusions are described in more detail below:

- **Plant nutrients and trace elements:** Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as *"plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants"* [40 CFR 152.6(g)(1)]

- **Plant inoculants:** Plant inoculants are *"...products consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system"* [40 CFR 152.6(g)(2)].

- **Soil amendments:** Soil amendments (which include soil additives and soil conditioners) are *"...products containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth"* [40 CFR 152.6(g)(3)].

- **Vitamin-hormone products:** A vitamin-hormone product is defined as: *"A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under section 2(v) of FIFRA, provided it meets the following criteria:*

  *(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and*

  *(2) The product is not intended for use on food crop sites, and is labeled accordingly."*

  [40 CFR 152.6(f)(1)(2)]

The following sections of this document provide tables that list:

(Table 1) substances generally considered by the Agency to be plant nutrients and trace elements, plant inoculants, soil amendments, and vitamin-hormone products;

(Table 2a) examples of non-pesticidal (*i.e.* non-plant regulator) product label claims associated with each one of the exclusions from the FIFRA Section 2(u) definition of a plant regulator;

(Table 2b) examples of generic product label claims generally considered "non-pesticidal" (*i.e.* non-plant regulator claims) by the Agency, that are not associated with any particular regulatory exclusion or product application/use site;

(Table 3) a list of plant regulator active ingredients contained in EPA-registered products having modes of action that trigger regulation under FIFRA as a pesticide; and

(Table 4) examples of plant regulator claims associated with EPA-registered plant regulator end-use products that trigger regulation under FIFRA as a pesticide.

**Table 1. Substances generally considered by the Agency to be plant nutrients and trace elements, plant inoculants, soil amendments, and vitamin-hormone products. These substances are excluded from FIFRA Section 2(v) Definition of Plant Regulator**

**Plant Nutrients and Trace Elements**

- Three primary macronutrients (N, P, K)
- Three secondary nutrients (Ca, S, Mg)
- Micronutrients/trace elements (B, Cl, Co, Cu, Fe, Mn, Mo, Ni, Na, Zn); in some plants: Al, Vn

**Plant Inoculants (Any microorganism applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system)** [1, 2] Examples include:

- *Azospirillum spp.* [3]
- *Azotobacter spp.* [3]
- *Bradyrhizobia spp, and Rhizobia spp.* [3]
- Mycorrhizal fungi [3]
- Strains /isolates of other genera of microorganisms with no known pesticidal properties
- Composites of two or more of the above

**Soil Amendments (substance or substances intended for the purpose of improving soil characteristics favorable for plant growth)** [1] Examples include:

- Composts, mulches, and vermicomposts (as described in the AAPFCO Manual).
- Peat, perlite, vermiculite, gypsum, kaolin
- Garden/landscape/potting soils
- Microbes intended to produce a physical/chemical/biological (non-pesticidal) change in the soil

**Vitamin-Hormone Products (a mixture of plant hormones, plant nutrients, inoculants, or soil amendments). Not considered a plant regulator if the following two criteria are satisfied:**

- The product, in the undiluted package concentration at which it is distributed or sold, is classified in Toxicity Categories III or IV
- The product is not intended for use on food crop sites, and is labeled accordingly.
- Examples include: products used as root dips or on non-food bearing ornamental trees and shrubs

[1] Not a comprehensive list; other non-pesticidal substances and non-pesticidal microbes could be included.
[2] Strains or isolates that have known pesticidal activity and/or are EPA-registered Microbial Pesticides may not be included [see section entitled Microbes in Plant Biostimulant (PBS) Products in this document]
[3] Agrees with European Commission list of microbes that may be included in PBS

**Table 2a. Examples of product label claims generally considered "non-pesticidal" *(i.e.* non-plant regulator claims) by the Agency[1]. Claims are listed for each exclusion from the plant regulator definition, except for nutritional chemicals[2] and vitamin-hormones[3]**

**<u>Plant Nutrition-based Claims</u> (necessary to normal growth of plants and in a form readily useable by plants)**

- Avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders (*e.g.* including, but not limited to: blossom end rot, chlorosis, necrosis, discoloration, stunting, etc.)
- Increases overall plant mass
- Increases plant/crop size/yield
- Improves/supports plant/seed health/strength/vigor
- Improves/supports root/shoot/foliage/fruit/nut growth/vigor
- Improves/supports asymbiotic/symbiotic microbial associations with plant roots and rhizosphere
- Increases plant strength
- Increases/improves root growth
- Optimizes conditions for plant growth
- Optimizes conditions for seed germination
- Optimizes conditions for tolerance of/resistance to abiotic stress

**<u>Plant Inoculant-based Claims</u> (enhance availability/uptake of plant nutrients through root system)**

- Enhance/improve/support/beneficial microbes in rhizosphere/soil microbiome
- Increases overall plant mass by improved nutrient uptake
- Increases/improves/optimizes conditions for better germination and early seed growth
- Increases/improves/optimizes conditions root and shoot growth
- Increases/improves/optimizes conditions for tolerance of/resistance to abiotic stress by improved nutrition
- Improve/increase/support biodegradation of organic matter
- Improve/increase/support availability/release of bound nutrients from the soil
- Improve nutrient/water transport/uptake/efficiency by plants/roots
- Improve/support mychorrhizal/rhizobial association/symbiosis with plant roots
- Improve/support nodulation
- Improves/increases optimizes conditions for overall plant health by better nutrition
- Improve/support plant/root growth/vigor by better nutrition
- Improves Phosphorous solubilization/availability for improved uptake [4]
- Reduces Phosphorous loss to the environment [4]
- Reduces/protects against abiotic/biotic stress by improved nutrient/water uptake/availability

| **Table 2a. Examples of product label claims generally considered "non-pesticidal" *(i.e.* non-plant regulator claims) by the Agency[1]. Claims are listed for each exclusion from the plant regulator definition, except for nutritional chemicals[2] and vitamin-hormones[3]** |
|---|
| **<u>Soil Amendment-based Claims</u> (intended for the purpose of improving soil characteristics favorable for plant growth)** [5]<br>• Buffers/changes soil pH<br>• Changes cation exchange capacity (CEC)<br>• Creates/improves soil/plant root environment to improve/support seed germination/root growth<br>• Helps condition the soil for improved plant performance<br>• Increases/improves/optimizes conditions for plant vigor<br>• Increases/improves/optimizes conditions for tolerance of/resistance to abiotic stress<br>• Increases/improves/optimizes conditions for overall plant healthIncreases yield potential<br>• Improves/increases water/nutrient availability/use efficiency/processing/retention<br>• Improves/increases soil/water nutrient retention/holding capacity/permeability<br>• Provides/supplies organic matter<br>• Reduces leaching<br>• Reduces soil compaction<br>• Supports beneficial microbes/ augments activity and function of beneficial microbes |
| [1] Not a comprehensive list and may include other synonymous terms<br>[2] Nutritional chemicals are not defined in this document.<br>[3] Claims for vitamin-hormone products are not listed in this table. Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(g) (1) & (2).<br>[4] May include other plant nutrients and trace elements listed in Table 1.<br>[5] Soil amendments may include microbes intended for purposes of improving soil characteristics favorable for plant growth |

**Generic Product Label Claims for Products Not Covered by the Exclusions from the FIFRA Section 2(v) Definition of a Plant Regulator.** The Agency recognizes that the exclusions from the definition of a plant regulator, as listed under FIFRA Section 2(v), may not cover all current or proposed product applications or use sites for plant biostimulants. Table 2b provides a list of generic product label claims generally considered "non-pesticidal" (*i.e.* non-plant regulator claims) by the Agency. These claims are not associated with any particular regulatory exclusion or product application/use site. These claims may not be added to a plant biostimulant product label unless they are fully compliant with 40 CFR 152.15.

**40 CFR 152.15. Pesticide products required to be registered.** Generally, No person may distribute or sell any pesticide product that is not registered under the Act, except as provided in §§152.20, 152.25, and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, *i.e.*, use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

Part (c) of this regulatory provision is particularly important. It states that if the distributor/seller of a substance (in the context of this document, a plant biostimulant product) has actual or constructive knowledge that the substance will be used, or is intended for use as a pesticide (*i.e.* a plant regulator), it will be subject to regulation as a pesticide under FIFRA.

**Table 2b. Examples of generic product label claims generally considered "non-pesticidal" *(i.e.* non-plant regulator claims) by the Agency, that are not associated with any particular regulatory exclusion or product application/use site [1, 2]**

- Alleviates/avoids/corrects/prevents nutrition-based/nutrient deficiency-based plant disorders
- Enhances/aids/supports/helps/improves abiotic stress tolerance
- Enhances/aids/supports/helps microbial populations
- Increases plant efficiency
- Enhances/aids/supports/helps/improves conditions for greater plant size or mass
- Helps the plant realize its true yield potential
- Improves/aids/supports/helps/enhances conversion of applied nutrients to plant available forms
- Improves efficiency of applied fertilizers
- Improves nutrient uptake via natural chelating/complexing agents
- Improves/aids/supports/helps/enhances conditions for better plant establishment
- Improves/aids/supports/helps/enhances overall plant health
- Improves overall plant nutrition
- Improves/increases/aids/supports/helps/enhances plant vigor
- Increases plant nutrient assimilation efficiency
- Increases/aids/supports/helps/enhances/optimizes soil conditions for greater root mass
- Increases/aids/supports/helps/enhances/improves tolerance of and/or resistance to abiotic stress
- Increased tolerance to sodium (Na)
- Optimizes/aids/supports/helps/enhances/improves conditions for more bloom or fruit size
- Optimizes conditions for germination, establishment, and plant growth
- Optimizes efficiency of plant nutrition and pesticide treatment
- Promotes/aids/supports/helps optimize conditions for greater root and shoot growth
- Promotes/aids/supports/enhances stronger plants
- Protects plants/leaves from burning with over-application of foliar nutrients (and burning effects of salt)
- Recovers crops affected by stress due to inefficient management
- Reduces lodging
- Supports nutrient uptake
- Supports/aids/helps nutrient uptake to prevent, mitigate, or correct a specific plant nutrient disorder
- Supports/optimizes conditions for better vegetative growth

[1] Product claims may not state or imply that the plant biostimulant product, through physiological action, accelerates or retards the rate of growth, accelerates or retards the rate of maturation, or otherwise alters the behavior of plants or the quality of the produce thereof.

[2] Product claims must be compliant with 40 CFR 152.15

**Plant Regulators and Product Label Claims:** In determining what natural substances are considered plant regulators, and what may constitute a plant regulator claim on a product label, the mode of action of the substance(s) and associated label claim(s) must be congruent with the intent of the plant regulator definition (see Appendix I). Based solely on the FIFRA section 2(v) "plant regulator" definition, a naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

1. Accelerate or retard the rate of [plant] growth
   - Includes individual plant organs (*e.g.* flowers, fruits, etc.).

2. Accelerate or retard the rate of [plant] maturation
   - Includes individual plant organs (*e.g.* flowers, fruits, etc.).

3. Or otherwise alters the behavior of plants or the produce thereof.
   - Includes changes in plant growth habit/architecture (*e.g.* foliage, fruit size, shape, numbers, etc.)

Table 3 lists current EPA-registered, naturally-occurring, plant regulator active ingredients having modes of action and associated product label claims that are consistent with the FIFRA definition of a plant regulator.

**Table 3. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide [1, 2, 3]**

- Abscisic Acid (ABA)
- *gamma*-Aminobutyric Acid (GABA)
- 6-Benzyladenine (6-aminopurine; a cytokinin)
- Chitin and Chitosan [4]
- Choline
- Complex Polymeric Polyhydroxy Acids (including Humic acid, fulvic acid, tannins; & organic acids from Leonardite) [5]
- Corn glutens/Corn gluten meal
- Cytokinins (as all isopentenyladenine and zeatin derivatives) [6]
- Cytokinin (as kinetin)
- Ethylene
- Gibberellic Acid $A_3$ ($GA_3$)
- Gibberellic Acid $A_4$/ $A_7$ ($GA_{4+7}$)
- L-Glutamic Acid
- Harpin proteins [4]
- Homobrassinolide
- Indole-3 Acetic Acid (IAA)

| **Table 3. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide [1, 2, 3]** |
|---|
| • Indole-3-Butyric Acid (IBA)<br>• Jasmonates (includes all derivatives of jasmonic acid) [4]<br>• Lysophosphatidylethanolamine (LPE)<br>• Laminarin<br>• 1-Octanol<br>• Potassium silicate [4]<br>• *Saccharomyces cerevisiae* extract (Brewer's Yeast extract) [4]<br>• Salicylic Acid [4]<br>• Seaweed Extracts [7]<br>• Sodium o-nitrophenolate<br>• Sodium p-nitrophenolate<br>• Sodium guaiacolate |
| [1] Some EPA-registered microbial pesticides are registered as plant regulators or have plant regulator claims listed on their product labels<br>[2] Includes Biochemical and Microbial Induced Resistance Promoters<br>[3] This list only includes naturally-occurring plant regulators contained in EPA-registered products; it does not include substances under review by the Agency or known plant regulators for which no products have been proposed, but that may have plant regulator activity<br>[4] EPA-registered Induced Resistance Promoter<br>[5] Foliar applications only, soil applications may be excluded as a soil amendment in the absence of any pesticidal claims (including plant regulator claims)<br>[6] Isopentenyladenine derivatives are typically produced by microbes; zeatin derivatives are typically produced by plants<br>[7] Seaweed extracts (SWE) are heterogenous mixtures of naturally-occurring plant regulators (Battacharyya et. al., 2015; Craigle, 2011; Stirk and Tarkowska, 2003; Stirk et. al., 2014); products containing active ingredients derived from SWE have been registered by the Agency as plant regulator products (see Appendix II) |

Conventional chemical plant regulators are not listed in Table 3. If a conventional chemical is contained within a PBS product, it likely would be considered a Conventional Chemical pesticide by the Agency and not a PBS.

Table 4 lists examples of plant regulator product label claims for current EPA-registered biochemical plant regulators that are consistent with the FIFRA Section 2(v) plant regulator definition.

**Table 4. Examples of Plant Regulator Claims Associated with EPA-registered Plant Regulator End-Use Products that Trigger Regulation Under FIFRA as a Pesticide [1]**

**Accelerates or retards rate of plant growth:**

- Enhances/promotes/stimulates fruit growth & development
- Enhances/promotes/stimulates plant growth & development
- Enhance/inhibit development
- Promote stem elongation
- Root/shoot stimulator
- Stimulates cell division, cell differentiation & cell enlargement

**Accelerates or retards rate of [plant] maturation:**

- Accelerates/controls/delaysabscission/development/ripening/senescence
- Induce/promote/retard/suppress flowering
- Induce/promote/retard/suppress bud break
- Induce/promote/retard/suppress seed germination

**Alters the behavior of plants:**

- Controls suckering
- Improves plant/tree structure
- Induces resistance/induced resistance promoter (to pathogens/pests)
- Inhibits sprouting
- Inhibit/reduce/promote/stimulate ethylene production
- Stimulates nutrient uptake & nutrient utilization

**Alters the produce [of plants]**

- Enhances/promotes crop/fruit/produce color/development/quality/shape
- Enhances/promotes fruit growth & development
- Fruit & nut thinner/sizer

[1] Not a comprehensive list and may include other synonymous terms that influence growth development, maturation, and quality changes in plants

**Microbes in PBS Products:** Microbes are components of many PBS products and it is well documented that microbes synthesize plant regulators that are secreted into the plant root growth zone *(i.e.* the rhizosphere) and subsequently taken up by plants (Le Mire *et. al.* 2016; Van Loon, 2007). Microbial products that make specific plant regulator claims on their product labels, and are intended for use on food crops, are not excluded from regulation under FIFRA as vitamin-hormone products because

of their intended use on food crop sites. In addition, if a PBS product contains microbial strains and/or isolates for species that have been reported in the scientific literature, in patent applications, or elsewhere as having pesticidal activity and/or are currently registered as microbial pesticides by the Agency, they may be regulated by the Agency as microbial pesticides, regardless of whether plant regulator or other pesticidal claims are made in connection with the distribution or sale of the product.

Similarly, if the PBS product consists of or contains one or more microbial active ingredients and has no significant commercially valuable use as distributed or sold other than use for pesticidal (*i.e.* plant regulator) purpose (by itself or in combination with any other substance); or the distributor or seller has actual or constructive knowledge that the PBS product will be used, or is intended to be used, for a pesticidal (*i.e.* plant regulator) purpose, the product may still be considered a pesticide and regulated as such [40 CFR 152.15]. Demonstration of commercially valuable uses would have to show that the plant biostimulant claims (such as making plant nutrients more available to the plant) were the actual cause of the plant growth effect (such as increased yield) as opposed to a pesticide cause (such as disease or insect suppression).

**SUMMARY**

The guidance is intended to help establish which biochemical substances and mixtures, and associated product label claims are or are not considered to be plant regulators by the Agency and, therefore, subject to regulation under FIFRA as pesticides. This guidance does not address or attempt to provide a regulatory definition for "plant biostimulant" or for "nutritional chemical." As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice.

**References**

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**APPENDIX I: Federal Plant Regulator Definition and Exclusions**

Plant regulators are defined in FIFRA Section 2(v)], as *"...any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof...."*

Excluded from the plant regulator definition are those products that are "Products intended to aid the growth of desirable plants" including: (1) plant nutrients, trace elements, nutritional chemicals, (2) plant inoculants, (3) soil amendments; and vitamin-hormones [40 CFR 152.6(g)]. For purposes of this discussion:

Plant nutrients are "...products consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants [40 CFR156.6(g)(1)];

Plant inoculants are *"...products consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system"* [40 CFR 152.6(g)(2)];

Soil amendments (which would include soil additives and soil conditioners) are *"...products containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth"* [40 CFR 152.6(g)(3)]; and

Vitamin-hormone products are: *"A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under section 2(v) of FIFRA, provided it meets the following criteria:*

> *(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of §156.62 of this chapter for Toxicity Category III or IV; and*
>
> *(2) The product is not intended for use on food crop sites, and is labeled accordingly."*

[40 CFR 152.6(f)(1)(2)]

Nutritional chemicals is a term that is not defined either in FIFRA or in the Code of Federal Regulations.

Plant Biostimulant is a term that is not defined either in FIFRA or in the Code of Federal Regulations.

**APPENDIX II: Examples of EPA-registered Products that are Derived From Seaweed Extracts.**

Cytoplex HMS (EPA Registration Number 58199-7

Cytex (EPA Registration Number 35980-1)

Cytogro Hormone Biostimulant (EPA Registration Number 90022-1)